IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC.,	:	**CIVIL ACTION**
	:	
Plaintiff,	:	
	:	
v.	:	**No. 2:06-cv-2768**
	:	
CEPHALON, INC., et al.,	:	
	:	
Defendants.	:	

ORDER

AND NOW, this 5th day of August, 2015, upon consideration of "Apotex's Fed. R. Civ. P. 72(a) Objections to the Magistrate Judge's Order and Memorandum Opinion Concerning Gordon Fahner (Dkt. Nos. 811 and 812); In the Alternative, Apotex's Motion to Clarification" (Doc. No. 824), and "Defendants' Joint Response to Apotex's Fed. R. Civ. P. 72(a) Objections to the Magistrate Judge's Order and Memorandum Opinion Concerning Gordon Fahner (Dkt. Nos. 811 and 812)" (Doc. No. 829) and "Apotex's Reply in Support of Dkt. No. 824" (Doc. No. 837), I find as follows:

I. FACTUAL AND PROCEDURAL HISTORY

1. On May 5, 2014, I referred "Defendants' Joint Motion to Exclude Testimony of Plaintiff Apotex, Inc.'s Fed. R. Evid. 701 Witness Gordon Fahner" to Magistrate Judge David R. Strawbridge for disposition. Judge Strawbridge issued a Memorandum Opinion and Order on October 1, 2014 granting Defendants' motion and excluding the following lay opinions of Gordon Fahner, an Apotex employee: (1) The Food and Drug Administration ("FDA") issues which purportedly prevented Apotex from entering the market until 2014

would not have impeded the launch, re-launch or sale of modafinil in the but-for world; and (2) Modafinil would have ranked among Apotex's top five commercial priorities for re-launch in 2011 following the removal of a FDA Import Alert in the but-for world.

2. Judge Strawbridge's opinion sets out the relevant background regarding Mr. Fahner's proposed testimony as follows:

> Apotex, in the real world, was precluded from launching its modifinal product in December 2006 by what it alleges to be Cephalon's anti-competitive acts despite having received tentative approval for a launch from the FDA. For the purpose of demonstrating its economic loss, Apotex has modeled a but-for world that approximates the profits it says it would have made if the Apotex modifinal were not kept off the market by the actions of the defendants. The parties acknowledge that the but-for world must take into account the real world circumstance that the FDA placed an import alert banning the sale of products in the United States that were manufactured at two Canadian sites, Etobiocoke and Signet Drive, where Apotex manufactured its modifinal product between August 2009 and July 2011.
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> In anticipation of its re-launch after July 2011, Apotex organized a steering committee to plan the re-launch at the two facilities. Fahner, who is the Vice President of Business Operations and Finance, had previously taken on "the responsibilities of the Vice President of Supply Chain" and was a member of the committee responsible for managing, ranking, and prioritizing the re-launch of Apotex's products after the import ban. The committee evaluated its products considering a number of factors, and then prioritized the order in which they would re-launch these products. The factors considered in coming to its prioritization decision included: sales of the product before the import alert, the potential opportunity in the marketplace after re-launch, the number of competitors in the market, and the dynamic of the generic market without Apotex in 2010.
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> In August 2012, the FDA inspected Apotex's Signet facility and identified violations of the current good manufacturing practice regulations. As a result, it issued a Warning Letter, which, in the real world, precluded Apotex from obtaining final approval for U.S. sales from the FDA until February 2014.
>
> Since actual sales of modafinil before the import alert are not available, Fahner considered the projections of Apotex's expert witness to opine that modafinil would have been part of the re-launch plan in 2010. Fahner's

> challenged testimony further concluded that (1) in the but-for world, modafinil would have ranked among the company's top five commercial priorities for re-launch after the lifting of the import ban, and (2) the FDA issues that have allegedly prevented Apotex's entry over the last two years would not have impeded the launch, re-launch, and sale of modafinil.

(Mem. Op. pp. 2-3.)

3. On October 22, 2014, Apotex filed objections to Judge Strawbridge's Opinion and Order. In its objections, Apotex argued that Judge Strawbridge's conclusion that Mr. Fahner's reprioritization opinion was unreliable and unhelpful was based on an impermissible weighing of evidence and that the conclusion that Mr. Fahner lacked the requisite experience to opine on the impact of the 2013 FDA Warning Letter was based on a misapplication of law.[1] Alternatively, Apotex seeks clarification that the Opinion and Order does not preclude Apotex from presenting factual testimony from Mr. Fahner.[2]

II. LEGAL STANDARDS

4. Under Federal Rule of Civil Procedure 72(a), non-dispositive pretrial matters may be referred to a magistrate judge for review and decision. A party may serve and file objections to an order entered by a magistrate judge pursuant to Rule 72(a) and the "district judge in the case must consider timely objections and modify or set aside any

[1] Apotex also objects that "Judge Strawbridge confused the experience required to opine on the impact of the 2013 FDA Warning Letter with the experience required to opine on Apotex's re-launch prioritization." I find it unnecessary to reach this argument because I find that Mr. Fahner's prioritization opinion was erroneously excluded on other grounds and meets the requirements for admissibility. Nonetheless, I agree with Apotex's contention that the reprioritization opinion is distinct from the second opinion regarding the impact of the 2013 FDA Warning Letter.

[2] Defendants respond that a ruling on the admissibility of any fact testimony from Mr. Fahner is more appropriately reserved until trial. I agree with Defendants and note nothing set out in the Opinion and Order can be read as excluding Mr. Fahner's fact testimony. As such, Apotex's motion for clarification is denied.

part of the order that is clearly erroneous or is contrary to law." Id.; see also 28 U.S.C. § 636(b)(1)(A).

5. A finding is clearly erroneous "when the district court, reviewing the record before the magistrate judge, is left with the definite and firm conviction that a mistake has been committed." In re Processed Egg Prods. Antitrust Litig., 2014 WL 6388436, at *3 (E.D. Pa. Nov. 17, 2014) (citations and quotation marks omitted). An order is contrary to law "if the magistrate judge has misinterpreted or misapplied applicable law." Id.

6. Lay witness testimony in the form of an opinion is admissible if it is: "(a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. The first requirement – that the opinion be "rationally based on the perception of the witness" – "demands more than that the witness have perceived something firsthand; rather, it requires that the witness's perception provide a truly rational basis for his or her opinion." Asplundh Mfg. Div. v. Benton Harbor Engr., 57 F.3d 1190, 1201 (3d Cir. 1995). The "second requirement—that the opinion be 'helpful to a clear understanding of the witness's testimony or the determination of a fact in issue'—demands more than that the opinion have a bearing on the issues in the case; in order to be 'helpful,' an opinion must be reasonably reliable." Id.

7. Rule 701 "was primarily designed to allow lay individuals to express opinions that are in reality only a shorthand statement of fact." Id. at 1193. These circumstances can include the "identification of an individual, the speed of a vehicle, the mental state or

responsibility of another, whether another was healthy, the value of one's property, and other situations in which the differences between fact and opinion blur and it is difficult or cumbersome for the examiner to elicit an answer from the witness that will not be expressed in the form of an opinion." Id. at 1197-98.

8. Rule 701 has been expanded to allow lay witnesses to offer certain economic and business related opinions. See, e.g., Donlin v. Philips Lighting N.A. Corp., 581 F.3d 73, 81 (3d Cir. 2009). For example, in Joy Mfg. Co. v. Sola Basic Industries, Inc., 697 F.2d 104 (3d Cir. 1982), the United States Court of Appeals for the Third Circuit held that, in an action for damages resulting from the failure of two furnaces, the district court abused its discretion in excluding the testimony of the plaintiff's supervisor of production control concerning the percentage of plaintiff's losses that resulted from the failure of the furnaces. Id. at 110. The court reasoned that the witness' opinion was rationally based on his "extensive personal knowledge of [the plaintiff's] plants, its on-going heat treating processes, and the two furnaces in question." Id. at 111-12. Similarly, an accountant has been permitted to offer an opinion, as a lay witness, as to a company's lost profits in light of his "very particular and quite extensive prior experience with [the company's] books." Asplundh Mfg. Div, 57 F.3d at 1202 (citing Teen-Ed, Inc. v. Kimball Intern., Inc., 620 F.2d 399, 403-04 (3d Cir. 1980).

9. However, such testimony is inadmissible under Rule 701 where it is not based on the witness' personal experience or knowledge or where the calculations required are "sufficiently complex." Donlin v. Philips Lighting N.A. Corp., 581 F.3d 73, 82 (3d Cir. 2009). For example, in an employment discrimination case, the court held that the district

court abused its discretion in allowing the plaintiff to offer an opinion as to her front pay damages. Id. Specifically, the Third Circuit concluded that the plaintiff's testimony was inappropriate regarding estimates as to annual pay raises, pension values, and the probability of death. Id. at 82-83. The Third Circuit reasoned that the plaintiff was only a temporary employee, lacked in depth knowledge of the company's "salary structure, advancement opportunities, pay raises, or employment patterns" and the opinions she offered "required forward-looking speculation for which she lacked the necessary training." Id. at 83.

III. LEGAL ANALYSIS

Fahner's Opinion Regarding the Impact of the 2013 FDA Warning Letter

10. Judge Strawbridge determined that Mr. Fahner lacked the requisite experience with or knowledge of regulatory affairs to opine on the impact that the 2013 FDA Warning Letter would have had on Apotex's modafinil sales efforts in the but-for world. Judge Strawbridge noted that Mr. Fahner's opinion was based on hearsay information from colleagues in Apotex's regulatory department and that Mr. Fahner admitted that he had no personal involvement or contact with the FDA at any point during his tenure with Apotex.

11. Apotex argues it was error to focus on Mr. Fahner's lack of personal interaction with the FDA because requiring personal involvement is inconsistent with United States v. Polishan, 336 F.3d 234 (3d Cir. 2003). In Polishan, the Third Circuit held that "[a] witness testifying about business operations may testify about 'inferences that he could draw from his perception' of a business's records, or 'facts or data perceived' by him in

his corporate capacity." Id. at 242 (citing Teen-Ed, Inc., 620 F.2d at 403-04). The Third Circuit has since clarified that it has "consistently required that lay testimony requiring future projections of a business or operation come from someone who has intimate and thorough knowledge of the business gathered from either a lengthy tenure or a position of authority." Donlin, 581 F.3d at 81.

12. Apotex contends that, based on Polishan, Mr. Fahner is qualified to opine on the impact that the 2013 FDA Warning Letter would have had in the but-for world in light of his "access to materials" and "day-to-day experience" at Apotex. However, access to materials and day-to-day experience does not invariably mean that one has acquired an intimate knowledge of the business gathered through a lengthy tenure. Nonetheless, even if access to materials and day-to-day experience satisfied the standard set forth in Donlin, Judge Strawbridge correctly concluded that while Mr. Fahner has substantial experience in finance and supply chain management, this experience is not germane to the opinion he seeks to offer regarding the impact of the 2013 FDA Warning Letter. Indeed, Mr. Fahner testified that he would have to consult with Apotex's "regulatory affairs" department to determine what impediments might prevent modafinil from obtaining final FDA approval. (Ford Decl. Ex. 7, 2011 Fahner Dep. p. 214.) Apotex has failed to demonstrate that Mr. Fahner possesses the relevant "intimate and thorough knowledge of the business gathered from either a lengthy tenure or a position of authority" that would render his opinion admissible. See Donlin, 581 F.3d at 81. As such, Judge Strawbridge's decision to exclude Mr. Fahner's opinion regarding the impact of the 2013 FDA Warning letter was not clearly erroneous or contrary to the law.

Fahner's Opinion Regarding the Re-Launch Prioritization

13. Judge Strawbridge also determined that Mr. Fahner's opinion regarding the re-launch prioritization in the but-for world did not meet Rule 701's helpfulness or reliability requirements. In reaching this conclusion, Judge Strawbridge noted that Mr. Fahner posited that Apotex would have secured up to 20% of the modafinil market in the but-for world while Apotex's principal damage expert, Dr. Hal J. Singer, opined that Apotex would only have secured a 7.5% market share. Additionally, Judge Strawbridge noted that Apotex stated in a separate legal proceeding that the FDA Import Alert had a devastating effect on Apotex's ability to increase market share and goodwill upon its 2011 re-launch. Judge Strawbridge concluded that these pieces of evidence contradicted Mr. Fahner's re-prioritization opinion rendering it unreliable and unhelpful to a jury.

14. Apotex urges that it was clear error to conduct an admissibility ruling by making factual determinations as to conflicting evidence on just one factor considered in Mr. Fahner's opinion – i.e. market share. On this point I agree with Apotex.

15. While Mr. Fahner's testimony can certainly be questioned based on the inconsistencies highlighted above, I find that Apotex satisfied the Rule 701 requirements and that it was clear error to exclude Mr. Fahner's testimony based on what is in essence a question regarding the opinion's weight or persuasive value. See Fisher v. Dominion Transmission, Inc., 2015 WL 1505656, at *8 (M.D. Pa. Apr. 1, 2015) (so long as a lay witness's opinion meet the Rule 701 requirements whether the witness's "observations, opinions and inferences are incorrect is an issue for [the opponent] to pursue on cross-examination. It is not, however, grounds to keep [a witness's] testimony from being heard

at all.") Apotex adequately demonstrated that Mr. Fahner possessed the requisite experience and personal knowledge under Rule 701 to offer an opinion as to the likely date that generic modafinil would have been re-launched in the but-for world. Mr. Fahner served on the steering committee that considered drugs for re-launch in the real world. In that capacity, he participated in an evaluation of Apotex's products and prioritized those products for re-launch based on a number of factors including sales of the product before the FDA Import Alert, the marketplace upon re-launch, the number of generic competitors, and the dynamics of the market without Apotex. Mr. Fahner applied these same considerations to offer an opinion as to where modafinil would have ranked in this re-launch process had Apotex obtained final approval for modafinil in 2006.

WHEREFORE, it is hereby **ORDERED** that "Apotex's Fed. R. Civ. P. 72(a) Objections to the Magistrate Judge's Order and Memorandum Opinion Concerning Gordon Fahner (Dkt. Nos. 811 and 812); In the Alternative, Apotex's Motion to Clarification" (Doc. No. 824), are **GRANTED in part and DENIED in part** as follows:

- Apotex's objection to the Opinion and Order as to Mr. Fahner's testimony regarding the impact of the 2013 FDA Warning Letter is **OVERRULED**.
- Apotex's objection to the Opinion and Order as to Mr. Fahner's testimony regarding Apotex's modafinil reprioritization in the but-for world is **GRANTED**.

BY THE COURT:

/s/ Mitchell S. Goldberg

Mitchell S. Goldberg, J.